



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0352; FRL-9419-01-OCSP]

Nitrapyrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of nitrapyrin in or on cottonseed, crop subgroup 20C; cotton, gin byproducts; cotton, meal; rice, grain; and rice, straw. Corteva Agrosciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0352, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (202) 566-0294.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status

information on EPA/DC services and access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Anita Pease, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: ADFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the *Federal Register*'s e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-

HQ-OPP-2021-0352 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0352, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 24, 2021 86 FR 47275 (FRL-8792-02-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8875) by Corteva Agrosciences, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.350 be amended by establishing

a tolerance for combined residues or residues of the nitrification inhibitor nitrapyrin and its metabolite, 6-chloropicolinic acid (6-CPA), in or on cottonseed crop subgroup 20C; cotton, gin byproducts; cotton, meal; rice, grain; and rice, straw at 4.0, 0.6, 6.0, 0.03 and 0.15 parts per million (ppm), respectively. That document referenced a summary of the petition prepared by Corteva Agrosciences, the registrant, which is included in the docket. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for a tolerance for combined residues or residues of nitrapyrin and its metabolite, 6-chloropicolinic acid (6-CPA), in or on cottonseed crop subgroup 20C; cotton, gin byproducts; cotton, meal; rice, grain; and rice, straw at 4.0, 0.6, 6.0, 0.03 and 0.15 parts per million (ppm), respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting

sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for nitrapyrin, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to nitrapyrin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged. On August 27, 2019, EPA published in the *Federal Register* a final rule establishing tolerances for residues of nitrapyrin in or on sugar beet molasses, sugar beet roots, sugar beet tops, rapeseed seed, and the vegetable, tuberous and corm, crop subgroup 1C. See (85 FR 48651) (FRL-10009-42). That document contains a summary of the toxicological profile, assumptions for dietary exposure assessment, cumulative risk, and the safety factor for children, which have not changed. More detailed information on the subject action to establish a tolerance in or on cotton and rice can be found in the document titled, “Nitrapyrin. Human Health Risk Assessment for New Uses in/on Cotton and Rice,” dated December 8, 2021 by going to <https://www.regulations.gov>. The referenced document is available in the docket EPA-HQ-OPP-2021-0352.

Toxicological profile. For a discussion of the Toxicological Profile of nitrapyrin, see Unit III of the August 12, 2020 rulemaking (85 FR 48651) (FRL-10009-42). There have been no changes to the toxicological endpoints since the last risk assessment.

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for nitrapyrin, see the document titled: “Nitrapyrin. Human Health Risk Assessment for New Uses in/on Cotton and Rice,” dated December 8, 2021,

in docket number EPA-HQ-OPP-2021-0352.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of nitrapyrin on cotton and rice. The assessment used the same assumptions as the August 12, 2020 final rule concerning tolerance-level residues, default processing factors for all processed commodities, and 100 percent crop treated.

Drinking water exposure. EPA has revised the nitrapyrin drinking water assessment since the August 12, 2020 final rule. Surface water and groundwater modeling were simulated using the Pesticide in Water Calculator (PWC version 2.0; Sep. 18, 2020) for use on cotton. The Pesticides in Flooded Applications Model (PFAM; version 2.0; Sep. 27, 2016) was also used in surface water modeling for use on rice. The highest estimated drinking water concentrations (EDWCs) are 124 µg/L for acute exposure and 111 µg/L for chronic exposure from ground water sources based on the Florida (FL) central ridge model scenarios.

Non-occupational exposure. There are no currently registered or proposed residential uses for nitrapyrin; therefore, residential handler and post-application exposure and risks were not assessed.

Cumulative exposures. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to nitrapyrin and any other substances and nitrapyrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that nitrapyrin has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III of the August 12, 2020 final rule for a discussion of the Agency's rationale for that determination.

Aggregate risk and determination of safety. EPA determines whether acute and chronic

dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

The acute dietary (food and water) risk estimates are below EPA's level of concern for all population subgroups (<100% of the acute population adjusted dose (aPAD)). The population subgroup with the highest acute risk estimate is all-infants (<1 year-old), at 14% of the aPAD.

The chronic dietary (food and water) risk estimates are below HED's level of concern for all population subgroups (<100% of the chronic adjusted population dose (cPAD)). The population subgroup with the highest chronic risk estimate is children (1 to 2 years old) at 26% of the cPAD.

Since there are no registered residential uses, the acute and chronic aggregate exposure and risk assessment are equivalent to the dietary (food and drinking water) exposure and risk estimates and are below EPA's level of concern (<26 % of the cPAD). Nitrapyrin is classified as "not likely to be carcinogenic to humans at doses that do not result in constitutive androstane receptor (CAR) activation as indicated by *Cyp2b10* expression". Therefore, the chronic dietary endpoint and assessment are protective of all chronic risks, including potential carcinogenic effects. More detailed information can be found at <https://www.regulations.gov> in the document titled "Nitrapyrin. Human Health Risk Assessment for the Section 3 Registration Action for New Uses on in/on Cotton and Rice," dated December 8, 2021 by going to <https://www.regulations.gov>. The referenced document is available in the docket EPA-HQ-OPP-2021-0352.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection) is available to enforce the tolerance expression. Seven analytical methods are available in Volume II of the Pesticide Analytical Manual (PAM II—Pesticide Reg. Sec. 180.350) for tolerance enforcement for nitrapyrin and/or for metabolite 6-CPA.

B. International Residue Limits

Codex and Canada have not established maximum residue limits (MRLs) for residues of nitrapyrin. Therefore, there are no issues related to international harmonization. A summary of the MRLs can be found in Appendix D of the document titled “Nitrapyrin. Human Health Risk Assessment for the Section 3 Registration Action for New Uses on in/on Cotton and Rice,” dated December 8, 2021 by going to <https://www.regulations.gov>. The referenced document is available in the docket EPA-HQ-OPP-2021-0352.

C. Revisions to Petitioned-for Tolerances

Rice straw is no longer considered a significant livestock feed item and a tolerance is therefore unnecessary. Additionally, tolerance values for cottonseed crop subgroup 20C, cotton, gin byproducts and cotton meal are being established consistent with the Agency’s rounding class practice.

V. Conclusion

Therefore, tolerances are established for the residues of nitrapyrin in or on cottonseed crop subgroup 20C at 4 parts per million (ppm); cotton, gin byproducts at 0.6 ppm; cotton, meal at 6 ppm; and rice, grain at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled

“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 19, 2022.

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.350, amend the table in paragraph (a) by adding a table heading and, in alphabetical order, the entries “Cottonseed subgroup 20C”; “Cotton, gin byproduct”; “Cotton, meal”; and “Rice, grain” to read as follows:

§ 180.350 Nitrapyrin; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	* *
Cottonseed subgroup 20C	4
Cotton, gin byproduct	0.6
Cotton, meal	6
* * * * *	* *
Rice, grain	0.03
* * * * *	* *

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